REMARKS

I. Priority is Perfected Within Four Months

When the present application was filed, an indication of the amendment to claim priority was provided. This is reflected in the Filing Receipt from the P.T.O. In the present document, the amendment to the specification is perfected to comply with 37 C.F.R. § 1.121. This is being done within four months of the September 23, 2003 filing date of the present application.

II. Divisional Status

The present application is a divisional of U.S. application Serial No. 09/700,967 ("the '967 application"; Attorney Docket No. 4100.001400), which issued as U.S. Patent No. 6,624,141 on September 23, 2003. The inventorship remains the same as the parent application.

The '967 application was filed under 35 U.S.C. § 371, with a Preliminary Amendment that revised the claims from the PCT application. Claims 1-8, 14-24, 35-46, 48-50 and 52-68 were pending when the '967 application was filed and were subject to a six-way restriction requirement. The claims of the Group I invention were elected without traverse and progressed to issue. Applicants reserved the right to pursue claims directed to the non-elected inventions in a divisional application, and reserved the right to traverse aspects of the restriction requirement other than as applied to the Group I invention.

When the present divisional application was filed, the claims drawn to the Group I invention were canceled. Presently, the claims of the Group II and VI inventions have been amended, such that these inventions have been effectively withdrawn without traverse.

Claims of the Group III, IV and V inventions remain, which are not patentably distinct. The present application is therefore a divisional application directed to the inventions originally

set forth as Group III, IV and V, which in fact constitute a unified invention. The Group IV (claim 57 only) and Group V (claim 58 only) inventions are unified with the Group III invention, as methods of ameliorating an effect of heparin or low molecular weight heparin (Group IV), and for treating or preventing undue or excessive bleeding (Group V), are species within the methods of inactivating heparin or low molecular weight heparin of the Group III invention. The examination of the Group IV and V inventions can also be conducted without additional burden on the Office as the addition of Groups IV and V adds only two claims.

III. Status of the Claims and Fees

On filing the present divisional, the Request canceled claims 1-8, 14-24, 35-46 and 52-54 of the '967 application, such that claims 48-50 and 55-68 were pending. Presently, claims 48-50, 55 and 57-67 have been amended, to establish unity and introduce language in accordance with the claims that issued from the parent application. No claims have been added or canceled.

Claims 48-50 and 55-68 are therefore in the case. The application has three independent claims and 17 total claims. Accordingly, no excess claim fees are required. The filing fee and surcharge are provided herewith.

IV. Compliance with 37 C.F.R. § 1.121 and § 1.115

Applicants respectfully request that the preceding amendments to the specification and claims be entered prior to substantive examination of this application. All of the amendments are fully supported by the parent applications to which priority is claimed.

The claim for priority has been timely introduced into the specification by amendment of the opening paragraph at page 1. The amendments to the specification comply with the revisions to 37 C.F.R. § 1.121. According to the revisions to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

The amendments are enterable, being submitted promptly after filing the application, and will not unduly interfere with the preparation of a first Office Action. The changes will not require significant time for review or cause an undue burden. Entry of the amendments is therefore proper under 37 C.F.R. § 1.115.

V. The Claims are Allowable

The claims allowed in the parent application are directed to purified protamines with defined characteristics, compositions, combinations and kits thereof and methods of preparation. The present divisional application is directed to methods of inactivating heparin or low molecular weight heparin using the purified protamines of the parent application, including methods of ameliorating effects of heparin or low molecular weight heparin, such as for treating or preventing undue or excessive bleeding.

As the purified protamine and composition claims in the parent application have been allowed, and the present divisional is directed to methods of using purified protamines defined in the same terms, the present claims are also in condition for allowance. Given that all requirements of patentability have been addressed in the parent application, and the presently claimed methods can be practiced without undue experimentation by those of ordinary skill in the art in light of the present disclosure, Applicants respectfully request that the claims be directly progressed to allowance.

A Terminal Disclaimer is not necessary to secure allowance, as this is a proper divisional application filed in response to a Restriction Requirement entered by the Office under 35 U.S.C. § 121.

VI. Additional Support for the Claims

As described above, the present claims are directed to methods of inactivating heparin or low molecular weight heparin using purified protamines of defined properties. Independent claims 55, 57 and 58 have been revised to define the purified protamines in the same terms as allowed in claim 1 in the '967 application.

The other claims have been revised to reflect certain embodiments from the claims allowed in the parent application. In addition to allowed claim 1, particular support for each of the pending claims exists in the allowed claims, as summarized below.

Claims 48, 49 and 50 define the purified protamines as having molecular weights of between about 400 and about 2000 Daltons, between about 500 and about 1350 Daltons and between about 1100 and about 1300 Daltons, respectively. These are supported by allowed claims 4, 6 and 7 in the parent application, respectively.

Each of claims 59-63 have been revised to depend from claim 64, which now recites administration to a mammal that has or is at risk for developing excessive bleeding. This also conforms to the restriction requirement in the '967 application, in which claims 59-63 were included with the Group III invention, rather than with claim 58 of the Group V invention

Claims 65 and 66 define the purified protamines as having molecular weights of about 1300 and about 1200 Daltons, respectively. These are supported at least by allowed claims 70 and 8 in the parent application, respectively.

Claim 67 defines the composition as comprising at least a first and at least a second purified protamine. This is supported at least by allowed claim 15 in the parent application.

It will therefore be understood that no new matter is included within any of the pending claims.

VII. Formalities

Formal drawings are enclosed herewith. Applicants' initial duty of disclosure is also met, with the enclosed courtesy copies of 1449s from the parent application and Information Disclosure Statement to make the issued patent of record.

No fees should be due in addition to the enclosed filing fees. However, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4100.001482.

VIII. Conclusion

In conclusion, Applicants submit that, in light of the foregoing remarks, the present claims define a unified invention that is in condition for allowance and an early indication to this effect is respectfully requested. Should the Examiner have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,
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